

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:  
Mark J. Ratain *et al.*

Serial No.: 10/057,834


Filed: January 25, 2002

For: COMPOSITIONS AND METHODS FOR  
OPTIMIZING UGT2B7 SUBSTRATE  
DOSINGS AND FOR PREDICTING  
UGT2B7 SUBSTRATE TOXICITY

Group Art Unit: 1634

Examiner: Unknown

Atty. Dkt. No.: ARCD:358US

CERTIFICATE OF MAILING 37 C.F.R. 1.8	
I hereby certify that this correspondence is being deposited with the U.S. Postal Service with sufficient postage as First Class Mail in an envelope addressed to: MS AMENDMENT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date below:	
March 28, 2005	
Date	Gina N. Shishima

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

**MS AMENDMENT**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450

Sir:

In compliance with the duty of disclosure under 37 C.F.R. § 1.56, it is respectfully requested that this Supplemental Information Disclosure Statement be entered and the documents listed on attached Form PTO-1449 be considered by the Examiner and made of record. Copies of the listed documents required by 37 C.F.R. § 1.98(a)(2) are enclosed for the convenience of the Examiner.

In accordance with 37 C.F.R. §§ 1.97(g), (h), this Supplemental Information Disclosure Statement is not to be construed as a representation that a search has been made, and is not to be

construed to be an admission that the information cited is, or is considered to be, material to patentability as defined in 37 C.F.R. § 1.56(b).

To comply with 37 C.F.R. § 1.98(a)(3)(i), I am providing a concise explanation of the relevance of B2 and B7, which I understand are patent applications not in English. An English translation of the abstract for each application is provided. These translations were obtained as part of the record for these applications from search databases.

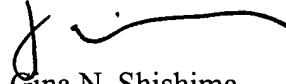
B2 is included on the 1449 because it was believed to have been either cited or identified during the prosecution of an application unrelated by priority to the present case but related by inventorship (Mark Ratain). A translation of the remainder of the application has not been obtained because it does appear applicable to the current application based on the English abstract.

B7 is included on the 1449 because the English abstract was identified in a search for patents and patent applications concerning UGT polymorphisms. A translation of the remainder of the application has not been obtained because the abstract discloses polymorphisms in exons of UGT1, and not noncoding regions of the gene. Thus, it is relevant to the extent it concerns UGT1A polymorphisms.

A fee as set forth in 37 C.F.R. § 1.17(p) in the amount of \$180.00 is enclosed. If an appropriate check has not been enclosed, or if it is insufficient, the Commissioner is authorized to deduct the appropriate fees from Fulbright & Jaworski L.L.P. Account No.: 50-1212/ARCD:358US.

Applicants respectfully request that the listed documents be made of record in the present case.

Respectfully submitted,



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Date: March 28, 2005

Form PTO-1449 (modified)

Atty. Docket No.  
ARCD:358USSerial No.  
10/057,834

List of Patents and Publications for Applicant's

Applicant  
Mark J. Ratain *et al.*

INFORMATION DISCLOSURE STATEMENT

(Use several sheets if necessary)

Filing Date:  
January 25, 2002Group:  
1634U.S. Patent Documents  
*See Page 1*Foreign Patent Documents  
*See Page 1*Other Art  
*See Page 2*

## U.S. Patent Documents

Exam. Init.	Ref. Des.	Document Number	Date	Name	Class	Sub Class	Filing Date of App.
	A3	2002/0061518	5/28/02	Penny and Galvin	435	6	5/05/99
	A4	2003/0077629	4/24/03	Galvin <i>et al.</i>	435	6	7/24/02
	A5	2003/0099960	5/29/03	Ratain <i>et al.</i>	435	6	1/25/02
	A6	2003/0099977	5/29/03	Guida and Kurth	435	6	7/26/02
	A7	2003/0157517	8/21/03	Penny and Galvin	435	6	9/18/02
	A8	2004/0058363	3/25/04	Hasegawa <i>et al.</i>	435	6	6/12/03
	A9	2004/0076968	4/22/04	Acuna <i>et al.</i>	435	6	7/02/01
	A10	2004/0121327	6/24/04	Manns and Strassburg	435	6	1/03/02
	A11	2004/0203034	10/14/04	Ratain <i>et al.</i>	435	6	1/05/04
	A12	6,395,481	5/28/02	Di Rienzo <i>et al.</i>	435	6	2/16/99
	A13	6,448,003	9/10/02	Guida and Kurth	435	6	6/08/99
	A14	6,472,157	10/29/02	Di Rienzo <i>et al.</i>	435	6	2/01/02
	A15	6,479,236	11/12/02	Penny and Galvin	435	6	5/05/99
	A16	6,586,175	7/01/03	Galvin <i>et al.</i>	435	6	7/20/99

## Foreign Patent Documents

Exam. Init.	Ref. Des.	Document Number	Date	Country	Class	Sub Class	Translation Yes/No
	B2	EP 0919244	6/2/99	Europe			Abstract
	B6	EP 1352970	10/15/03	Europe			English
	B7	JP 2004-073035	3/11/04	Japan			Abstract
	B8	WO 01/79230	10/25/01	WIPO			English
	B9	WO 02/053770	7/11/02	WIPO			English
	B10	WO 02/057410	7/25/02	WIPO			English

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EXAMINER:

DATE CONSIDERED:

EXAMINER: INITIAL IF REFERENCE CONSIDERED, WHETHER OR NOT CITATION IS IN CONFORMANCE WITH MPEP609; DRAW LINE THROUGH CITATION IF NOT IN CONFORMANCE AND NOT CONSIDERED. INCLUDE COPY OF THIS FORM WITH NEXT COMMUNICATION TO APPLICANT.

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*See Page 1*Other Art  
*See Page 2*

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Exam. Init.	Ref. Des.	Document Number	Date	Country	Class	Sub Class	Translation Yes/No
	B11	WO 02/06523	1/24/02	WIPO			English
	B12	WO 2003/013536	2/20/03	WIPO			English
	B13	WO 2003/013537	2/20/03	WIPO			English
	B14	WO 2004/016814	2/26/04	WIPO			Abstract
	B15	WO 97/32042	9/04/97	WIPO			English
	B16	WO 99/57322	11/11/99	WIPO			English

## Other Art (Including Author, Title, Date Pertinent Pages, Etc.)

Exam. Init.	Ref. Des.	Citation
	C196	Ando <i>et al.</i> , "UGT1A1 genotypes and glucuronidation of SN-38, the active metabolite of irinotecan," <i>Annals of Oncology</i> , 9:845-847, 1998.
	C197	Beutler <i>et al.</i> , "Racial variability in the UDP-glucuronosyltransferase 1(UGT1A1) promoter: a balanced polymorphism for regulation of bilirubin metabolism," <i>Proc. Natl. Acad. Sci., USA</i> , 95:8170-8174, 1998.
	C198	Clarke <i>et al.</i> , "Genetic defects of the UDP-glucuronosyltransferase-1 (UGT1) gene that cause familial non-hemolytic unconjugated hyperbilirubinemias," <i>Clinica Chimica Acta</i> , 266:63-74, 1997.
	C199	De Morais <i>et al.</i> , "Decreased glucuronidation and increased bioactivation of Acetaminophen in Gilbert's syndrome," <i>Gastroenterology</i> , 102:577-586, 1992.

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